UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

NEUROGRAFIX, a California corporation; and WASHINGTON RESEARCH FOUNDATION, a not-for-profit Washington corporation,

Plaintiff,

v.

SIEMENS MEDICAL SOLUTIONS USA, INC., a Delaware corporation; and SIEMENS AKTIENGESELLSCHAFT, a German corporation,

Defendant.

Case No. 10-CV-1990 MRP (RZx)

CLAIM CONSTRUCTION ORDER

I. INTRODUCTION

Neurografix accuses Siemens Medical Solutions USA, Inc. and Siemens Akteingesellschaft (collectively, "Siemens") of violating its U.S. Patent No. 5,560,360 (the "Filler patent") (filed Mar. 8, 1993) by Siemens' marketing or creation of various hardware and software products capable of T2 MR neurography, diffusion weighted neurography, diffusion anisotropy imaging, diffusion tensor imaging, and DTI tractography. Docket No. 112, Ex. 2 [Plaintiff Neurografix's First Amended Disclosure of Asserted Claims and Infringement Contentions] at 2-3. As a first step in determining patent infringement, this Court

construes the essential terms of the Filler patent. Additionally, Siemens urges this Court to find certain terms in the Filler patent indefinite under 35 U.S.C. § 112, ¶ 2 or unsupported by an algorithmic disclosure under § 112, ¶ 6. The Court considers those arguments as part of this claim construction.

II. BACKGROUND

The Filler patent is directed to a method of utilizing magnetic resonance systems (commonly known as MRI) to create images of nerves in the body. The patent describes various ways of using MRI to achieve the improved conspicuity of part of the nerve. These include T2 processing, fat suppression, and diffusion weighting. Additionally, the patent discloses the use of vector processing. Although many of these methods existed in the prior art, the examiner reviewing the patent allowed the claims because "[t]he prior art of record [did] not teach or reasonably suggest the inclusive subject mater of claim [1] which includes a method of using mri to determine the shape and position of mammal tissue, wherein the mammal tissue is a nerve consisting of a member from the group of peripheral nerves, cranial nerves numbers three through twelve, and autonomic nerves to provide a conspicuity of the nerve that is at least 1.1 times that of any adjacent non-neural tissue, without the use of neural contrast agents." Docket No. 102 [Joint Appendix of File History of Patent-In-Suit for Claim Construction Briefing] at JA00051.

III. APPLICABLE LAW

Claim construction generally begins with the court identifying the "ordinary and customary meaning" of a claim term as "the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*¸ 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citation omitted). The court identifies the claim term in the context of the claim in which it appears and the

context in which the claim term appears in relation to the other claims in the patent. *Id.* at 1314-15. The claims do not stand alone, thus the court must read the claims in light of the specification and prosecution history. *Id*. at 1315-18. The extrinsic evidence (for instance, expert testimony or references to contemporaneous dictionaries) can also provide insight into the meaning of a claim term but is less useful and persuasive than the intrinsic evidence. *Id*. at 1317. The court has the power and obligation to construe as a matter of law the meaning of language used in the patent claim. *See Markman v. Westview Instruments, Inc.*, 52 F.2d 967, 979 (Fed. Cir. 1995) (en banc).

A. Definiteness under 35 U.S.C. § 112, ¶ 2

35 U.S.C. § 112, ¶ 2 states, "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2 (2011). This ensures that the claims "delineate the scope of the invention using language that adequately notifies the public of the patentee's right to exclude." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005). If a claim were not sufficiently definite to inform the public of the bounds of the protected invention, competitors would be unable to avoid infringement. *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). Because an indefinite term may be impossible to construe, courts routinely decide definiteness issues during claim construction. Nevertheless, a court may determine that a definiteness issue is better addressed at a later point in the litigation.

In order to prove indefiniteness, the accused infringer must show by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history. *Id*. at 1249-50. A court may also consider whether the patent "expressly or at least clearly differentiates itself from specific prior art." *Id*. at 1252. But this

does not suggest that a claim that "reads on the prior art" is "never definite." *Id*. When a claim reads on the prior art, it can still be definite if a person of skill in the art can determine the boundaries of the claim. *See id.* When a claim reads on the prior art, or when a claim covers all future improvements, the focus is more appropriate on other validity challenges such as anticipation, enablement, or written description. *See id.* Indeed, the Federal Circuit in *Halliburton* recognized that the fact a claim distinguishes the prior art does not prove definiteness. *Id*. at 1253 ("even if the *'832 patent* distinguished 'fragile gels' of the invention from those of the prior art, it did not place any limit on the scope of what was invented beyond the prior art"). Thus, while a court should consider whether the patentee distinguished prior art to determine whether a claim is definite, the court's ultimate concern is whether a person of skill in the art would be able to determine the boundaries of the claim. *Id*.

B. Means-plus-function claims for general purpose computers

A slightly different issue arises when a patentee claims using a means-plus-function format.[1] When construing a means-plus-function claim, the court first identifies the particular claimed function. *Med. Instrumentation & Diagnostics Corp. v. Elektra AB*, 344 F.3d 1205, 1210 (Fed. Cir. 2003). Next, the court looks to the specification to identify the corresponding structure for that function. *Id.*

"In cases involving a computer-implemented invention in which the inventor has invoked means-plus-function claiming, [the courts have] consistently required that the structure disclosed in the specification be more than simply a general

[1] 35 U.S.C. § 112, ¶ 6 states, "[a]n element of a claim for a combination may be expressed as a means or step for performing a specified function without the recital of the structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6 (2011).

purpose computer or microprocessor." *Aristocrat Tech. Australia Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008). In these cases, the court must "[l]ook at the disclosure and determine if one of skill in the art would have understood that disclosure to encompass [an algorithm to perform the function] . . . ." *Id.* at 1337. A patentee will not satisfy § 112, ¶ 6 by simply asserting that a person of skill in the art would be able to write such a software program to achieve that function. *Id.*

Once the Court determines that the disclosure encompasses an algorithm, the Court must then determine whether that algorithm is "clearly linked" to the function in the claim. *See Med. Instrumentation & Diagnostics Corp.*, 344 F.3d at 1211.

C. Step-plus-function claims

Step-plus-function claims are authorized by the same source. *See* 35 U.S.C. § 112, ¶ 6 (2011). If the claim element uses the phrase "step for," then § 112, ¶ 6 is presumed to apply. *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 836, 850 (Fed. Cir. 1999). If the phrase does not appear in the claim, § 112, ¶ 6 is presumed not to apply. *Id.* But claim elements without express language may nevertheless be step-plus-function claims if they claim a function without a recitation of the acts for performing the function. *Id.* at 849. In order to show that § 112, ¶ 6 applies, a party seeking the finding must show that the limitation does not contain an act. *Masco Corp. v. United States*, 303 F.3d 1316, 1327 (Fed. Cir. 2002). Whether the limitation contains an act depends on whether the claim describes how to accomplish the function. *See Seal-Flex, Inc.*, 172 F.3d at 849-50.

IV. CLAIM CONSTRUCTION

A. Claim terms at issue

The parties dispute the meaning of the following claim terms:

1. “vector processing”
2. “a member of the group consisting of peripheral nerves, cranial nerves number three through twelve, and autonomic nerves”

Siemens alleges the following claim terms are indefinite under § 112, ¶ 2:

3. “controlling the performance of steps (a), (b), and (c) to enhance . . . the selectivity of said nerve”
4. “a conspicuity of the nerve that is at least 1.1 times that of [the] / [any adjacent] non-neural tissue”

The parties agree on the function for the following means-plus-function claim term but disagree on the scope of the algorithm disclosed by the patent:

5. “processor means coupled to said excitation and output arrangement means for processing said outputs to generate data representative of the diffusion anisotropy of the selected structure”

The parties agree on the functions of the following means-plus-function claim terms but the parties dispute which algorithms, if any, are linked to the claim:

6. “processor means is further for processing said data representative of the diffusion anisotropy of the selected structure to produce a data set that describes the shape and position of the selected structure”
7. “processor means . . . for: i) vector processing said outputs to generate data representative of anisotropic diffusion exhibited by the selected structure in the region, regardless of the alignment of said diffusion weighted gradients with respect to the orientation of said selected structure; and ii) processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy”
8. “said processing means is further for [calculating]/[determining] a further data set that describes the three dimensional shape and position of a segment of said [neural tissue]/[selected structure] by: analyzing the data representative of anisotropic diffusion to determine

how to relate said data set and said additional data sets describing the shape and position of cross sections of said [neural tissue]/[selected structure]; and based upon the results of said analyzing the data representative of anisotropic diffusion, combing said data set and said additional data sets to generate said further data set that describes the three dimensional shape and position of the segment of said [neural tissue]/[selected structure], thereby [allowing]/[enabling] a three dimensional shape and position of curved [neural tissue]/[structure exhibiting anisotropic diffusion] to be described"

The parties dispute whether the following claim terms are step-plus-function claims:

9. "processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy"
10. "a further data set that describes the three dimensional shape and position of a segment of said [neural tissue]/[selected structure] is generated by steps including: analyzing the data representative of anisotropic diffusion to determine how to relate said data set and said additional data sets describing the shape and position of cross sections of said [neural tissue]/[selected structure]; and based upon the results of said step of analyzing the data representative of anisotropic diffusion, combining said data set and said additional data sets to generate said further data set that describes the three dimensional shape and position of the segment of said [neural tissue]/[selected structure], thereby enabling the three dimensional shape and position of curved [neural tissue]/[structure exhibiting anisotropic diffusion] to be described"

B. Claim construction

1. "vector processing"

Neurografix's Construction	Siemens' Construction
Mathematical analysis of the data set to determine direction and magnitude of a	Calculating the ratio of D_{pl}/D_{pr} or calculating the data according to

given point (or voxel)	equation 3, 4, 5, and/or 6

Docket No. 103 [Plaintiff's Opening Claim Construction Brief ("Pl.'s Br.")] at 11; Docket No. 106 [Defendants' Responsive Claim Construction Brief ("Dfs.' Br.")] at 34.

Siemens alleges that "vector processing" is limited to specific equations disclosed in the Filler patent. Neurografix believes the term has a broader meaning. The parties' primary dispute appears to be whether the term "vector processing" includes the use of tensors. The Court holds that it does not.

Standing alone, the term "tensor" has a mathematical meaning. A tensor is an array of numbers of greater complexity than a vector. Neurografix's Claim Construction Demonstrative (hereinafter "Pl.'s Demo.") at slide 57 [PENGUIN DICTIONARY OF PHYSICS (V. Illingworth, ed. 1991)] ("A tensor of rank *r* has *n* to the *r* components."). Indeed, a vector is a subset of tensor. *Id.* ("a tensor of rank 1 is a *vector").

When the patentee applied for the Filler patent, he used only the word "vector" in the claims, even though he demonstrated that he knew tensors might be used as an alternative. *See* The Filler patent at 21:39-45. However, the patentee failed to claim tensors, and the term "vector processing" cannot be construed to cover tensors.

Nevertheless, the claim term is not limited to only the equations disclosed in the Filler patent. Siemens' construction would inappropriately import a limitation from the specification. *See Phillips*, 415 F.3d at 1319-20. The proper construction lies between the two definitions. The Court must recognize that the patentee chose the word "vector" rather than "tensor." It must also recognize that there might be other formulas for vector processing that do not follow the exact format described in the patent. If such equations exist, so long as they are not tensor based formulas, they may be appropriate and equivalent methods to determine the direction and magnitude of a given point or voxel. In order to satisfy these requirements, the

Court adopts the construction, "vector analysis (not tensor analysis) of the data set to determine direction and magnitude of a given point (or voxel)."

2. <u>"a member of the group consisting of peripheral nerves, cranial nerves number three through twelve, and autonomic nerves"</u>

Neurografix's Construction	**Siemens' Construction**
Neural tissue that is outside the arachnoid space, not including cranial nerves one and two (smell and vision). Commonly referred to as the peripheral nervous system as opposed to the central nervous system	A nerve that is listed in Taber's Cyclopedic Medical Dictionary (17th ed. 1993) on pages 182, 463 (excluding cranial nerves 1 and 2), 1290, and 1291 and/or that is otherwise not part of the central nervous system

Pl.'s Br. 5; Dfs.' Br. 17.

The primary dispute between the parties is whether the term includes nerves inside the arachnoid space. Neurografix primarily relies on arguments made by the patentee during prosecution to show that the claim is narrower than its plain and ordinary meaning. They rely on the patentee's prosecution statement:

> Claim 89 was drafted to intentionally exclude interpretation that would extend claim coverage to prior art methods and apparatus that: (1) are capable of imaging cranial nerves I (smell) and II (vision), which are actually an extension of the central nervous system with arachnoid, cerebrospinal fluid and dura mater, but (2) are not capable of imaging the recited peripheral nerves, cranial nerves three through twelve, or autonomic nerves ***that pass outside the arachnoid space (i.e. into the peripheral nervous system)*****.**

Pl.'s Br. 6 (emphasis added by the Plaintiff). They argue that this statement disclaimed nerves inside the arachnoid space.

This is not a clear disclaimer as is required under the law. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002) (prosecution history can overcome "heavy presumption that a claim term carries its ordinary and customary meaning" only if it shows "express intent to impart a novel meaning"). The words "pass outside" do not show an express intent to limit the claim term to only the neural tissue outside the arachnoid space. Instead, those words mean that the claim covers systems capable of imaging autonomic nerves that start inside the space and pass outside of that space. Thus, Neurografix's attempt to avoid the plain and ordinary meaning of the term fails.

Siemens' construction reflects the plain and ordinary meaning of the claim term. The Court construes the term to mean "a nerve that is listed in Taber's Cyclopedic Medical Dictionary (17th ed. 1993) on pages 182, 463 (excluding cranial nerves 1 and 2), 1290, and 1291 and/or that is otherwise not part of the central nervous system."

C. Indefiniteness

1. <u>"controlling the performance of steps (a), (b), and (c) to enhance . . . the selectivity of said nerve"</u>

Neurografix's Construction	Siemens' Construction
No construction necessary; or "controlling the performance of steps (a), (b), and (c) to enhance the ability to distinguish nerve from surrounding tissue"	Term not amenable to construction

Pl.'s Br. 16; Dfs.' Br. 8-9.

Siemens argues that this claim term is indefinite and suffers "the same fatal flaws as the 'fragile gel' limitation in *Halliburton*." Dfs.' Br. 10. Siemens' key complaint is that the term, if construed according to its plain and ordinary meaning,

covers "any pulse sequence or any other technique used in an MRI machine that enhances the recited nerves." Dfs.' Br. 9.

At the claim construction hearing, Neurografix's attorney confirmed this broad meaning:

> THE COURT: This step says you are to control the way you handle A, B and C to enhance the selectivity of the nerve, and so you just use your machine to do that?
>
> FENSTER: Yes. This patent in this step, the controlling step, is not limited to a particular method. It does cover any method that meets the limitation of enhancing the selectivity of the nerve. . . . [T]hat is the meaning of this claim, and there is nothing ambiguous about it. One of skill in the art knows whether they are controlling the parameters to enhance the selectivity of the nerve or not.

Claim Const. Tr. 42:3-15 (Mar. 24, 2011).

Siemens makes three points in support of its indefiniteness argument: 1) the plain and ordinary meaning does not distinguish the claims from the prior art, 2) the claims place no limit on the scope of what was invented, and 3) the controlling step has a functional element, and thus "fails to provide a clear-cut indication of [its] scope." Dfs.' Br. 10-11. These are simply variations of its key complaint that the term is too broad. Section 112, ¶ 2 is not directed to such complaints. Its purpose is to ensure that those persons of skill in the art understand when and how they might infringe a claim. If a patent claim is broad, but nevertheless clear, it is not indefinite.

A litigant has a difficult burden to show indefiniteness and this Court must go to great lengths to define a claim term. In *Exxon Research & Engineering Co. v. United States*, the Court of Appeals for the Federal Circuit said, "[i]f the meaning of [a] claim is discernible, even thought the task may be formidable," a court must find the claim definite. *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). "Only claims 'not amenable to

construction' or 'insolubly ambiguous' are indefinite." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005).

Siemens' arguments fail to persuade the Court that the term is insolubly ambiguous. Siemens first contends that because the claim term does not distinguish the claims from the prior art, it must be indefinite. But, as discussed above, *supra* section II.A, a claim can read on the prior art, yet be definite. Second, Siemens contends that because the claims place no limit on the scope of invention, the claims must be indefinite. But, as explained in footnote 5 of *Halliburton*, a claim may contain a limitation with no explicit upper bound at all. *Halliburton*, 514 F.3d at 1253 n.5. It is only when the limitation is ambiguous as to whether there is or is not an upper bound that the claim is indefinite. *Id.* Third, Siemens contends that the claim term includes a functional step and thus fails to provide a clear-cut indication of its scope. But on its own, the inclusion of a functional step does not lead to the conclusion that a claim is indefinite – a claim can use functional language and still be unambiguous.

Contrary to Siemens' contentions, the claim is not limitless nor are the bounds indeterminable. The claim term requires two things: the steps of (a), (b), and (c), must be controlled, and the selectivity of the nerve must be enhanced by that control. A person of ordinary skill in the art can easily understand that any time he controls those steps, and enhances the selectivity of the nerves, he meets those two limitations and is potentially infringing that part of the claim. Nothing in the specification, prosecution history, or submitted evidence indicates that this claim is any narrower than this plain meaning.

Because the claim is clear, the Court finds the term definite. Any method that controls the performance of steps (a), (b) and (c), and enhances the selectivity of the nerve, falls within the scope of this claim term.

2. <u>"a conspicuity of the nerve that is at least 1.1 times that of [the] / [any adjacent] non-neural tissue"</u>

Neurografix's Construction	**Siemens' Construction**
"Contrast (in, for example, intensity and color) between the nerve and [the]/[any adjacent] non-neural tissues is at least 1.1 times"	Term not amenable to construction

Pl.'s Br. 8; Dfs.' Br. 12.

This claim term is allegedly indefinite in a different way than "controlling the performance of steps (a), (b), and (c) to enhance . . . the selectivity of said nerve." In that claim term, Siemens argued that the term was so broad that it was not amenable to construction. *See* Dfs.' Br. 9. Here, Siemens contends that a person of skill in the art would be unable to ascertain how to calculate conspicuity. Dfs.' Br. 12.

Specifically, Siemens complains that the patentee did not specify which of many different methods should be used to calculate conspicuity. *Id.* at 13. They contend this renders the claim indefinite. Additionally, Siemens argues that even if the patent's disclosure of the method to calculate conspicuity is sufficient, the underlying determinations used in that method are wholly subjective which renders the claim indefinite. *Id.* at 14.

Neurografix contends that there are substantial issues of fact as to whether the claim term is indefinite and thus the question is properly left for the finder of fact. Pl.'s Br. at 10. But in *Exxon*, the Federal Circuit reminded the parties that "determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Exxon*, 265 F.3d at 1376. This Court adheres to that same principle and must examine whether this claim is indefinite.

Siemens argues that like the claims at issue in *Honeywell v. International Trade Commission*, 341 F.3d 1332 (Fed. Cir. 2003), there are multiple ways to calculate conspicuity necessitating that this Court find the term indefinite. In

Honeywell, the Federal Circuit determined that a patent disclosing a process to make polyethylene terephthalate yarn was indefinite for failing to disclose a method in which to calculate the melting point elevation of the product to determine whether it infringed. *Id.* at 1335. The Federal Circuit held that because claims, specification, and prosecution history failed to provide any guidance as to what method could be used to measure the melting point elevation of the product and because the method was necessary to discern whether a product had been produced using the claimed process, the claim was indefinite. *Id.* at 1340.

Honeywell is distinguishable. Instead of lacking any clue to discern which method is acceptable, the Filler patent expressly discloses one method for calculating conspicuity. It relates conspicuity to contrast, the Filler patent at 11:56-69, and gives an example of calculating nerve-to-muscle contrast by calculating the ratio of nerve image signal intensity to background image signal intensity, *id.* at 22:38-43. Given this example, the claim is not indefinite because of a failure to disclose a method for determining conspicuity. Indeed, the Court could, if required, use this clue to engage in the “formidable task” of discerning the meaning of the claim.

This inquiry may not be necessary if the claim term is indefinite for a different reason. All of the methods that calculate contrast, including the ratio method described above, seem to be based upon a subjective determination. In *Exxon*, the Federal Circuit noted that the “scope of claim language cannot depend solely on the unrestrained, subjective opinion of a particular individual purportedly practicing the invention.” *Exxon*, 265 F.3d at 1350. Because the claim term “aesthetically pleasing” was entirely subjective, the Federal Circuit found it indefinite. *Id.*

Here, Siemens makes a very persuasive showing that the underlying method of selecting a region of interest in the calculation of conspicuity is a subjective inquiry that renders the claim indefinite. If a person of skill in the art were to

determine the ratio between nerve signal image intensity to background image intensity, that person would be required to make a subjective determination as to which part of the image is nerve and which part of the image is background. That choice means the conspicuity calculation would necessarily be subjective and infringement would depend on who makes the measurement. *See* Docket No. 103, Ex. 1 [Expert Report of Michael E. Mosely], ¶¶ 33-34. This problem pervades all of Neurografix's conspicuity calculation methods.

Siemens' expert, Michael E. Mosely, explained that conspicuity would vary depending on "the subjective determination of which portion or portions of the structure to assess, for instance whether the observer chose to compare an entire nerve bundle or instead some substructure, and how the region of interest is selected for measurement." *Id*. at ¶ 33. He further explained that it would vary depending on "which portion or portions of the adjacent background to assess, for instance which non-neural tissue to assess and the selection of the particular background region of interest." *Id*. at ¶ 34. Mr. Mosely's report did not address whether users of the system – that is experts in that field – agreed on a method of making those selections or how experts decide which sections to select.

In contrast, Neurografix asserted that a "neuroradiologist, by training in line with their duty of care to the patient, will have great experience at identifying particular type of tissue in an image and selecting [a region of interest] representative of that tissue which is a standard task in that field of medicine." Docket No. 107 [Plaintiff's Reply Claim Construction Brief ("Pl.'s Reply")] at 5-6. The assertion is problematic because Neurografix failed to identify supporting evidence for it.

Because neither party addressed how a person of skill in the art would identify the nerve or the background, the Court declines to find the term indefinite or construe the term. If the parties pursue the issue, the parties must explain how skilled artisans distinguish those parts from each other.

D. The means-plus-function algorithm for claim 54(c)

1. "processor means coupled to said excitation and output arrangement means for processing said outputs to generate data representative of the diffusion anisotropy of the selected structure"

Neurografix's Construction	Siemens' Construction
Corresponding structure: (1) computer 72 and front-end circuit 74 (which the specification refers to as "processing system"); or (2) hosting processing system 32; and (3) their equivalents. If an algorithm is necessary, blocks 112 through 148 of Figures 9 and 10.	Corresponding structure: (1) computer 72 and front-end circuit 74, or host processing system 32, programmed to perform blocks 112 through 152 from Figures 9 and 10; and (2) equivalents thereof.

Pl.'s Reply at 16; Siemens' Claim Construction Demonstrative at slide 106.

This term appears in claim 54(c). The parties agree on a function for the claim but disagree over the specific algorithm disclosed for that function. In particular, the parties disagree whether blocks 150 and 152 are required. Blocks 150 and 152 direct the processing system to identify the perpendicular and parallel diffusion gradients and then subtract those gradients from each other such that a clear image of a nerve is revealed.[2]

The Court notes that the means-plus-function claims describe different types of data sets created by the algorithms in the patent. For this claim, the algorithm must create a data set that represents the selected structure's "diffusion anisotropy." The Filler patent at claim 54(c). This function is in contrast to the

[2] *See* The Filler patent, Fig. 9-10, 18:26-46, 15:51-57 ("For example, with gradients approximately perpendicular and parallel to the axis of the peripheral nerve at the particular point being imaged, the parallel gradient image can be subtracted from the perpendicular gradient image to produce the desired 'nerve only' image.").

data sets that describe the selected structure's "shape and position." *Id*. at claim 64. The first data set could be construed to include data representative of diffusion anisotropy in a given region for both nerve and non-nerve tissue. The second data set should have a higher level of differentiation between nerve and non-nerve tissue in order to describe the shape and position of the structure.

In order to understand the first data set and the meaning of claim 54(c), it is important to study the preferred embodiment and especially lines 15:33-18:65 of the Filler patent. Those lines describe the use of the MRI system to obtain two types of gradient images. The first image is derived from a gradient perpendicular to the axis of the nerve or a gradient is close to perpendicular. The second image is derived from a gradient parallel to the axis of the nerve or very nearly parallel. Once the system obtains these two gradients, the system subtracts them from each other to obtain a clearer image of the nerve.

Siemens contends that it is the result of this subtraction process that creates "data set representative of the diffusion anisotropy of the selected structure" and therefore, this claim requires blocks 150 & 152. Neurografix argues that blocks 112-148 create that data.

The Court finds claim 7 instructive. Claim 7 most clearly relates to the subtraction algorithm described in blocks 150 & 152.[3] That claim describes subtracting the perpendicular axis image and the parallel axis image to generate "a data set describing the shape and position of said nerve."[4] Because of this, the claim term at issue cannot include blocks 150 and 152. By the time the disputed algorithm performs block 148, the system has created data representative of the

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[3] *See* The Filler patent, claim 7 ("(a) exposing . . . [the] region to a magnetic polarizing field, . . . said magnetic polarizing field including a first diffusion-weighted gradient that is substantially parallel to the nerve and a second diffusion-weighted gradient that is substantially perpendicular to the nerve. . . (e) subtracting [the perpendicular output] from said [parallel output] to generate a data set describing the shape and position of said nerve.")

[4] *Id.*

structure's diffusion anisotropy. The subtraction steps of 150 and 152 exist to create data representative of the structure's shape and position.

The Court concludes that claim 54(c)'s linked algorithm is blocks 112 through 148 of Figures 9 and 10.

E. Means-plus-function claims in which the parties dispute which algorithms, if any, are linked to the claim

1. "processor means is further for processing said data representative of the diffusion anisotropy of the selected structure to produce a data set that describes the shape and position of the selected structure"

Neurografix's Construction	Siemens' Construction
Corresponding Structure: (1) computer 72 and front-end circuit 74; (2) host processing system 32; and (3) their equivalents If an algorithm is necessary, the algorithms described in block 152 of Figure 10 and 18:35-19:7 and 20:25-22:18 of the specification.	Corresponding Structure: (1) computer 72 and front-end circuit 74, or host processing system 32, programmed to perform blocks 112 through 154 from Figures 9 and 10 further programmed to divide the output of the subtraction process by signal information from a fat suppressed, t2-weighted spin echo sequence; and (2) their equivalents thereof

Pl.'s Reply 20; Dfs.' Br. 30.

The term in dispute appears in claim 64. The patent reveals a number of possible algorithms linked to the claim term. First, blocks 150–152 of figure 10 are a subtraction algorithm. *See supra* Part IV.D.1. That algorithm creates a data set that describes the shape and position of a selected structure. *Id.* The parties also agree that the patent discloses and links a T2-weighted echo sequence algorithm in lines 19:4-7 of the Filler patent. Pl.'s Reply 20-21, Dfs.' Br. 31.

Neurografix asserts that three or more algorithms are linked to this claim. First, the claim is linked to a "subtraction neurography" algorithm at lines 18:35-19:3. Pl.'s Reply 21. Additionally, the patent discloses a "threshold analysis" algorithm at lines 18:67-19:2. Finally, they contend that there are one or more "vector processing" algorithms linked in lines 20:25-22:18.

The subtraction neurography algorithm appears to be identical to the algorithm of block 150-152. Lines 18:35-65, which Neurografix cites in support of this algorithm, provide detail for the steps used in subtracting the perpendicular gradient image from the parallel gradient image. No other algorithms are disclosed in those lines.

The "threshold analysis" is not sufficiently disclosed because it is not enough to simply assert that a person of ordinary skill in the art knows how to apply it. The single sentence "[i]n some applications of known anisotropy, subtraction is unnecessary and can be foregone in favor of a threshold analysis[,]" is insufficient for a person of skill in the art to conclude that an algorithm is disclosed. That sentence wholly fails to tell a person of skill in the art how to apply the threshold analysis in the patent.

In oral argument, Neurografix claimed that there were four "vector processing" algorithms disclosed in lines 20:25-22:18. Neurografix's Claim Construction Demonstrative ("Pl.'s Demo.") at slides 70-71. For the reasons discussed below, *infra* Part IV.E.2, the Court holds those alleged algorithms are not sufficiently disclosed.

In its reply brief, Neurografix also argues that the equations (3) through (6) should be linked to claim 64. Pl.'s Reply 21. The Court concludes that a person of skill in the art would find those equations to be an algorithm. Next, the Court must determine whether the algorithm is sufficiently linked to claim 64.

Under the direction of *Medical Instrumentation*, the relevant inquiry is whether a person skilled in the art would actually understand that the relevant

portions of the specification describe algorithms for performing the claimed function. See *Med Instrumentation and Diagnostics Corp.*, 344 F.3d at 1212. The function of claim 64 is to process "data representative of the [selected structure's] diffusion anisotropy . . . to produce a data set that describes the [selected structure's] shape and position . . . ." Thus, the correct inquiry is whether a person of skill in the art would understand that equations (3) through (6) perform the function of determining a structure's shape and position from its diffusion anisotropy data.

Neurografix concedes that equations (3) through (6) are linked to the term "vector processing." Pl.'s Reply 17. "Vector processing" is used in claims 22, 36, 11, and 46. Each time the term appears, it is used in conjunction with generating data representative of the structure's "anisotropic diffusion." Because of this, a person of skill in the art would not conclude that equations (3) through (6) are linked to claim 64 – "vector processing" (and thus equations (3) through (6)) is never used to determine a structure's shape and position.

The Court concludes that claim 64 is linked to two algorithms; blocks 150-152, and the algorithm that divides the output of the subtraction process by signal information from a fat suppressed t2-weighted spin echo sequence.

2. <u>"processor means . . . for: i) vector processing said outputs to generate data representative of anisotropic diffusion exhibited by the selected structure in the region, regardless of the alignment of said diffusion weighted gradients with respect to the orientation of said selected structure; and ii) processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy."</u>

Neurografix's Construction	**Siemens' Construction**
Corresponding Structure: (1) computer 72 and front-end circuit	[(i) Equations 3 through 6 at 20:35-21:23 of the specification;

74; (2) host processing system 32; and (3) their equivalents If an algorithm is necessary: (i) the algorithms at 20:36-21:47 of the specification; (ii) the algorithms at 21:55-21:25[sic] of the specification.	(ii)] Corresponding structure: No corresponding structure disclosed, and term is not amenable to construction.

Pl.'s Reply 17; *See* Dfs.' Br. 24 ("The only one of these excerpts that actually describes a sufficiently precise algorithm that is clearly linked to how the processor means performs one of the recited functions is the explanation in the specification of using equations 3 through 6 to perform the vector processing function in element 55(c)(i).").

The claim term appears in claim 55(c). The parties agree on the function of the claim term, but disagree on whether an algorithm is disclosed and linked to claims 55(c)(i) and 55(c)(ii).

a) Claim 55(c)(i)

The parties agree that the algorithm, equations (3) through (6), defined in the Filler patent at 20:36-21:23, is linked to claim 55(c)(i). Pl.'s Reply 17; Dfs.' Br. 24. Neurografix argues that a tensor algorithm should also be linked to claim 55(c)(i). Pl.'s Reply 17. Because the Court holds that "vector processing" does not include the use of tensors, the tensor algorithm is not linked to claim 55(c)(i). *See supra* Part IV.B.1. Further, even if the tensor algorithm could be used, the tensor algorithm is not sufficiently disclosed in the patent.

Neurografix argues that a single sentence in the Filler patent provides enough disclosure for a person of ordinary skill in the art to conclude that the tensor algorithm is sufficiently disclosed. That sentence says, "[s]imilarly, tensor

analyses employing tensors of various ranks, as described in Basser et al., *Diagonal and Off Diagonal Components of the Self-Diffusion Tensor: Their Relation to an Estimation from the NMR Spin-Echo Signal*, SMRM BOOK OF ABSTRACTS 1222 (1992), can be used to treat, or transform the coordinates of, MR diffusional anisotropy data." The Filler patent at 21:39-45. Neurografix offered an exhibit as an illustration of this algorithm. Docket No. 107 [Ex. D to Supp. Weiss Decl.]. That exhibit provides three steps: (1) "use diffusion gradient info to calculate diagonal and off diagonal components of a matrix representing self-diffusion tensor," (2) "use matrix to calculate MR diffusional anisotropy data (effective vector)," and (3) "transform coordinates to get the orientation of the neural fibers." *Id*. References to the titles of prior art can provide a sufficient structure, but only if that title provides a structure sufficient for one of skill in the art. *Pressure Prods. Med. v. Greatbatch Ltd.*, 599 F.3d 1308, 1317 (Fed. Cir. 2010) (citing *Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1381 (Fed. Cir. 1999)). Here, the purported algorithm designed by Neurografix in exhibit D is not apparent from the title of the referenced work by Basser et al.[5] A person of skill in the art reading that title would not have understood that disclosure to encompass an algorithm.[6] The title fails to inform a person of skill in the art how to implement the algorithm created by Neurografix.

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[5] In support of its argument, Neurografix cites to Dr. Filler's expert report at ¶¶ 88-89. Docket No. 103, Ex. C. Those paragraphs are conclusory and do not illustrate how one of skill in the art would understand the title of the reference to be sufficient structure to support the algorithm designed by Neurografix.

[6] The Court of Appeals for the Federal Circuit recently issued *Rembrandt Data Tech., LP, v. AOL, LLC, et. al.*, No. 2010-1002 (Fed. Cir. Apr. 18, 2011) which overturned a district court's finding of invalidity for failure to disclose algorithms for means-plus-function claims.

The Federal Circuit stated that it disagreed with the district court regarding its findings in support of invalidity. *Id*. at *24 ("Drawing all reasonable inferences in favor of Rembrandt, we cannot agree with the district court that summary judgment of the invalidity of claims 1 and 2 of the '236 patent was warranted."). In reaching that decision, the Federal Circuit appears to have credited the appellant's expert witness' testimony. *See id.* ("Based on the expert testimony, there are genuine disputes of material fact regarding whether the specification discloses algorithms for

The Court thus adopts the equations 3 through 6, the Filler patent at 20:35-21:23, as the linked algorithm for claim 55(c)(i).

b) Claim 55(c)(ii)

Neurografix argues that claim 55(c)(ii) should be linked to algorithms found in the Filler patent at 21:55-22:25. Pl.'s Reply 20. During oral argument, Neurografix asserted that those lines reveal four algorithms. Those algorithms are (1) "connected voxel with thresholding," (2) "maximum anisotropy connection," (3) "'three dimensional' imaging technique," and (4) "supplement the previous algorithms with known path of structure." Pl.'s Demo. at slide 77.

Neurografix finds support for the first algorithm in lines 21:55-59.[7] Pl.'s Demo. at slide 77. They claim the algorithm has two steps: (1) "compare pixel intensity to image dependent threshold," and (2) "link/project results of 2D to form 3D image." *Id.* This algorithm is insufficient. It fails to describe how to compare the pixel intensity to the image dependent threshold or what that threshold is. Furthermore, it fails to describe how those results are linked. A person of skill in the art would not find this disclosure to be one of sufficient structure.

Neurografix's second[8] and third[9] algorithms rely on references to prior art to find sufficient structure. The Court holds that the title of the references and the

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'buffer means' and 'combining means.'"). This Court does not take those statements to mean that the Federal Circuit has changed its long standing precedent that a district court "has complete discretion to adopt the expert legal opinion as its own, to find guidance from it, or to ignore it entirely, or even to exclude it" when it construes a claim. *Markman*, 52 F.3d at 983. Because this Order addresses claim construction, the Court is free utilize extrinsic evidence as it sees fit.

[7] Those lines state, "[f]or example, the location of nerves in a given image plane can be detected by comparing pixel intensity to some threshold level. A three dimensional image can then be formed by linking or projecting the results of these two-dimensional analyses over the desired volume." The Filler patent at 21:55-59.

[8] That passage, in part, states "the direction of maximum anisotropy for each voxel associated with a nerve is determined and a voxel connection routine, of the type described in Saloner et al., *Application of a Connected-Voxel Algorithm to MR Anglographic Data*, 1 JOURNAL OF

passage at lines 21:60-22:5, and 22:6-17 do not disclose sufficient structure because neither describes what algorithm to implement or how to implement that algorithm. *See supra* Part IV.E.1.a.

Neurografix's final algorithm relies upon an "expert" system to predict the path of the structure.[10] The Filler patent at 22:21-25. Because the lines do not disclose how that system predicts the path of the nerve, a person of skill in the art would necessarily view it as an insufficient disclosure. This passage is not an algorithm.

Because a person of skill in the art would not understand the disclosures in lines 21:55-22:25 to disclose any algorithms, none of Neurografix's alleged algorithms constitute sufficient structure. The Court holds claim term 55(c)(ii) fails to meet the requirements of § 112, ¶ 6 and is thus indefinite.

3. <u>"said processing means is further for [calculating]/[determining] a further data set that describes the three dimensional shape and position of a segment of said [neural tissue]/[selected structure] by: analyzing the data representative of anisotropic diffusion to determine how to relate said data set and said additional data sets describing the shape and position of cross sections of said [neural tissue]/[selected structure]; and based upon the results of said analyzing the data representative of anisotropic diffusion, combing said data set and said</u>

MAGNETIC RESONANCE IMAGING 423-430 (1991), is then used to link up voxels of maximum anisotropy." The Filler patent at 21:64-22:3.

[9] "As an alternative to the two-dimensional imaging sequences described above, it is also possible to carry out the signal acquisition using a "three dimensional imaging sequence of the type described in Frahm et al., *Rapid Three-Dimensional MR Imaging using the FLASH Technique*, 10 JOURNAL OF COMPUTER ASSISTED TOMOGRAPHY 363-368 (1986). The output of this sequence is then processed using a three-dimensional Fourier transform to extract the returns from nuclei over the volume being imaged. The resultant processing used to compute D for a given voxel and to generate, for example, a subtraction angiogram is substantially the same as described above." The Filler patent at 22:6-17.

[10] It states, "[o]nce a given nerve has been identified in a given two-dimensional image, an 'expert' system 10 is able to predicate the occurrence of certain branches and mergers in this structure, albeit at unknown locations." The Filler patent at 22:21-25.

additional data sets to generate said further data set that describes the three dimensional shape and position of the segment of said [neural tissue]/[selected structure], thereby [allowing]/[enabling] a three dimensional shape and position of curved [neural tissue]/[structure exhibiting anisotropic diffusion] to be described.

Neurografix's Construction	**Siemens' Construction**
Corresponding Structure: (1) computer 72 and front-end circuit 74 (which the specification refers to as "processing system"); or (2) host processing system 32; and (3) their equivalents If an algorithm is necessary, the algorithms found at 21:55-22:5, 21:16-23, 19:33-38, and 21:60-22:5 of the specification.	Corresponding structure: No corresponding structure disclosed, and term is not amenable to construction.

Pl.'s Reply 22; Dfs.' Br. 24.

The claim term appears in claims 58 and 61. While the parties agree on the function of the claim terms, Siemens believes the Filler patent does not disclose an algorithm to satisfy the requirements of § 112, ¶ 6. Dfs.' Br. 24. Neurografix argues that the patent discloses four algorithms in lines 21:55-22:5, 21:16-23, 19:33-38, and 21:60-22:5 of the Filler patent's specification. Pl.'s Reply 22; Pl.'s Demo. at slides 80–81.

Neurografix argues that the specification discloses a "simple projection" algorithm in lines 19:33-38[11] that comprises the steps of (1) identifying conspicuous nerve, (2) linking the identified nerve cross-sections together, (3) and expressly linking through a "simple form of three-dimensional image generation." Pl.'s Demo. at slide 80. A person of skill in the art would not understand those lines to disclose how to link the sections or how to form the three-dimensional projection of the neural structure.

It next argues that the specification discloses a "connected voxel with thresholding" algorithm in lines 21:55-59. Pl.'s Demo. at slide 80. As discussed above, *supra* Part IV.E.1.b, the threshold algorithm does not provide sufficient disclosure in the specification.

It also argues that lines 21:60-22:5 disclose a "maximum anisotropy connection" algorithm. Pl.'s Demo. at slide 80. Again, as described above, *supra* Part IV.E.1.b, the passage relies on a reference that does not provide enough disclosure for a person of skill in the art to consider it an algorithm.

Finally, it argues that the specification discloses an "orientation contrast" algorithm in lines 21:16-23.[12] This passage has some differences from the previous passages and must be dealt with in more detail. As explained above, Siemens conceded that equations (3)-(6) are linked to claim 55(c)(i). Included in those lines is the passage at lines 21:16-23, which Neurografix claims is a separate

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[11] The specification states at lines 19:33-38, "[i]n a simple form of three-dimensional image generation, described in greater detail below, the high S/N ration of the two-dimensional neurograms produced by system **14** readily allows the imaged nerve cross-sections to be identified and then linked together to form a three-dimensional projection of the neural structure." The Filler patent at 19:33-38.

[12] The specification states, "As an alternative to the use of vector length images, arctan images can be employed. These images are obtained by establishing the intensity of a pixel in direct proportion to the angular output of one of the equations, (4), (5), or (6). An illustration of an arctan image is provided in Fig. 17. As shown in this example of a CNS neurogram, a select neural tract of interest can be effectively traced and made to stand out in isolation from other neural tracts." The Filler patent at 21:16-23.

algorithm linked to claims 58 and 61. In order for this passage to constitute disclosure of an algorithm, a person of skill in the art must understand this passage to perform the desired functionality of "[calculating]/[determining]" "a further data set that describes" "[the] [neural tissue's]/[selected structure's] three dimensional shape and position."

A person of skill in the art would not find this passage contains an algorithm to complete the desired function. Neurografix asserts that the "orientation contrast" algorithm has four steps: (1) "use arctan images from disclosed equations (4)-(6)," (2) "assign 'intensity of a pixel in direct proportion to the angular output,'" (3) "trace neural tract," and (4) "clearly linked 'a select neural tract of interest can be effectively traced.' " Pl.'s Demo. at slide 81. This passage fails to describe how, the neural tract is traced, and how, once traced, the data from the arctan images are turned into a data set representative of the three-dimensional shape and position of the structure.

Because the specification fails to disclose sufficient structures to support a finding that a person of skill in the art would consider them to be algorithms for this function, the Court holds that claims 58 and 61 are indefinite.

F. Step-plus-function claims

1. "processing said data representative of anisotropic diffusion to generate a data set describing the shape and position of said selected structure in the region, said data set distinguishing said selected structure from other structures in the region that do not exhibit diffusion anisotropy"

The claim, which appears in claim 36(e), describes a function (processing) but does not describe how to process the data. Because the claim term does not describe how to process the data, it does not have the requisite act and is thus a step-plus-function claim.

Siemens contends this term is subject to the same construction as the processor means limitation in claim 55. Dfs.' Br. 31. Because of this, Siemens contends that claim 36(e) is indefinite for failure to disclose an algorithm. Because the claim language in claim 36(e) is identical to claim 55(c)(ii), the Court finds claim 36(e) indefinite.

2. "a further data set that describes the three dimensional shape and position of a segment of said [neural tissue]/[selected structure] is generated by steps including: analyzing the data representative of anisotropic diffusion to determine how to relate said data set and said additional data sets describing the shape and position of cross sections of said [neural tissue]/[selected structure]; and based upon the results of said step of analyzing the data representative of anisotropic diffusion, combining said data set and said additional data sets to generate said further data set that describes the three dimensional shape and position of the segment of said [neural tissue]/[selected structure], thereby enabling the three dimensional shape and position of curved [neural tissue]/[structure exhibiting anisotropic diffusion] to be described"

This claim appears in claims 39, 46, and 49. For the same reasons stated above, these claims are step-plus-function claims.

The language of claims 39, 46, and 49 is identical to the relevant language in claims 58 and 61. Because claims 58 and 61 are indefinite for failure to disclose sufficient structure for a person of skill in the art to consider it an algorithm, claims 39, 46, and 49 are also indefinite.

V. CONCLUSION

The Court construes the following terms:

1. "vector processing" means "vector analysis (not tensor analysis) of the data set to determine direction and magnitude of a given point (or voxel)."
2. "a member of the group consisting of peripheral nerves, cranial nerves number three through twelve, and autonomic nerves" means "a nerve that is listed in Taber's Cyclopedic Medical Dictionary (17th ed. 1993)

on pages 182, 463 (excluding cranial nerves 1 and 2), 1290, and 1291 and/or that is otherwise not part of the central nervous system."

3. "controlling the performance of steps (a), (b), and (c) to enhance . . . the selectivity of said nerve" is not indefinite and has its plain and ordinary meaning.
4. Claim 54(c) is linked to the algorithm at blocks 112 through 148 of Figures 9 and 10.
5. Claim 64 is linked to two algorithms; blocks 150-152, and the algorithm that divides the output of the subtraction process by signal information from a fat suppressed t2-weighted spin echo sequence.
6. Claim 55(c)(i) is linked to the algorithm of equations 3 through 6 in the Filler patent at 20:35-21:23.
7. Claim 55(c)(ii) is indefinite.
8. Claims 58 and 61 are indefinite.
9. Claims 36, 39, 46, and 49 are step-plus-function claims.
10. Claims 36, 39, 46, and 49 are indefinite.

The Court declines to address the indefiniteness issue regarding conspicuity at this time. The Court presumes that the parties will wish to file motions for summary judgment at a later point. Accordingly, the Court will set a status conference to discuss the next steps in the case.

IT IS SO ORDERED.

DATED: May 05, 2011

Mariana R. Pfaelzer

Hon. Mariana R. Pfaelzer
United States District Judge